

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

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Testimony of Dr. Paul B. Thompson¹

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George Sternbach begins his history of anthrax by quoting passages from Virgil that describe an ancient plague in sheep and cows now presumed to have been an outbreak of the anthrax pathogen.² Anthrax is, in fact, one of many natural pathogens that affect both agriculture and human health.³ My testimony is intended to provide the Committee with background information on the way in which plant and animal diseases are approached within the context of agricultural science and veterinary medicine. My expertise is as an ethicist whose career has been devoted to the study of ethical issues as they arise in the context of agriculture and livestock production. There are two main points of focus that I would like to emphasize. First, agricultural production and food consumption are potential sources of exposure to diseases such as anthrax, as well as conduits between human and animal populations that can affect the transmissibility and virulence of pathogens. The risk profile of these pathogens that would be derived from an exclusive focus on human medicine or bioterrorism is thus potentially incomplete. Second, a straightforward appreciation of the ethical significance of the interaction between agriculture and human medicine or public health is constrained by institutional barriers that limit interaction among scientists and ethicists working in these respective fields.

Diseases of plants and animals can pose hazards to human beings. The routes of exposure include ingestion of pathogens when diseased organisms enter the food chain, forms of contagion associated with physical contact between diseased plants or animals and agricultural workers, and long distance transport of pathogens that originate in food and agricultural production through wind and water. In addition, agricultural plants and animals represent a possible route between disease processes that are uncontrolled or endemic in wild populations and the human population. However, agricultural production operates under procedures and regulations that have been developed to control risk to human populations. Indeed, these procedures may be so successful that people outside of agriculture and agricultural science may not realize how prevalent agriculturally based hazards have been for people in the past. Nevertheless, it is crucial to understand that ordinary crop production and animal

¹ I would like to acknowledge the assistance of Dr. John Baker, College of Veterinary Medicine, Michigan State University and Dr. Steve Halstead, State Veterinarian, Department of Agriculture and Rural Development, The State of Michigan in preparing my testimony. They should not be held responsible for remaining errors of fact or omission.

² George Sternbach, 2003. "The History of Anthrax" *The Journal of Emergency Medicine* 24: 463-467.

³ Gary Smith, "Animal Plagues: The Political and Economic Consequences of Noxoonotic Animal Diseases," in *Food Security in a Global Economy: Veterinary Medicine and Public Health*, G. Smith and A. Kelly, Eds. Philadelphia: 2008, University of Pennsylvania Press, pp. 61-71.

husbandry have the potential to vector existing pathogens and to provide a context in which evolution of new pathogens can occur.

Post-harvest contamination of food by micro-organisms such as e-coli O157:H7, salmonella and listeria is regarded as the most serious human health issue for the agricultural supply chain in industrial societies. These organisms do not present as disease in livestock species, but can contaminate food through movement of animal fecal matter through agricultural fields, water supplies and packing facilities. Some plant diseases such as aspergillus, fusarium and ergot fungi, are sources of foodborne illness. Inspection, monitoring and regulation have sharply curtailed the spread of infectious disease from plants and animals to humans. Nevertheless, supply chain transmission from animals to humans can occur, and anthrax is a case in point. The human deaths from anthrax in the Soviet city Sverdlovsk during 1979 were originally presumed to have been caused by consumption of anthrax infected meat. Only in 1996 did a review of the clinical and epidemiological evidence, which included a number of infected sheep, indicate that aerosol release from a military research installation was the likely cause of the Soviet anthrax deaths.⁴ One of the more bizarre instances of supply chain transmission occurs when hides of anthrax infected animals are harvested, as they occasionally are in less tightly regulated countries. Bongo players have apparently contracted cutaneous anthrax from their drums, and the deaths of drum makers in the United Kingdom have been attributed to inhalation of anthrax spores while handling hides.⁵

Although contagion from livestock to humans is not generally believed to a major issue in the United States, agricultural production practices necessarily bring human beings into direct physical contact with animals, and as such there are opportunities for transmission across species lines. Indeed, our word 'vaccination' is derived from a Latin root that means "from cows", owing to Edward Jenner's 18th century derivation of smallpox vaccines from the cow pox virus known to infect dairy maids.⁶ The large scale mechanization of agriculture reduced the historical amount of physical contact significantly, and the sheer percentage of national populations engaged in agriculture has declined from perhaps 80% in Jenner's day to approximately 1% in the United States today. Human contact with agricultural animals is a perennial concern for the control of fast mutating viruses that can switch hosts rapidly. Veterinarians monitoring avian influenza have been particularly attentive to the potential for crossovers between poultry and migrating flocks of wild birds.⁷ In addition, contact between animals and humans is important to human health in less developed countries, where it is estimated each cow infected with anthrax may result in up to 10 human cases of cutaneous disease.

⁴ M Meselson, J Guillemin, M Hugh-Jones, A Langmuir, I Popova, A Shelokov, and O Yampolskaya 1994. "The Sverdlovsk anthrax outbreak of 1979" *Science* 266 (5188), 1202-1208; D. H. Walker, O. Yampolska, and L. M. Grinberg. 1994. Death at Sverdlovsk: What Have We Learned? *American journal of Pathology*, 144, (6):1135-1141.

⁵ Hilary Hylton, 1974. "Haitian Bongos May Carry Anthrax," *The Palm Beach Post Times*, Sunday, April 21, p. B8; Chris Irvine, 2008. "Bongo drummer dies of anthrax," *The Telegraph* Accessed July 20, 2012 at: <http://www.telegraph.co.uk/health/3368306/Bongo-drummer-dies-of-anthrax.html>.

⁶ Nicolau Barquet, and Pere Domingo. 1997. "Smallpox: The Triumph over the Most Terrible of the Ministers of Death," *Annals of Internal Medicine* 127: 635-64.

⁷ Ilaria Capua, D. J. Alexander, Bruce A. Rideout and Marin Vincint. "The Changing Epidemiology of Avian Influenza," in *Food Security in a Global Economy: Veterinary Medicine and Public Health*, G. Smith and A. Kelly, Eds. Philadelphia: 2008, University of Pennsylvania Press, pp. 101-119.

Anthrax itself is not an important source of loss in U.S. livestock herds. Effective animal vaccines have long been available, though they are seldom used by most U.S. producers.⁸ Incidence of anthrax in livestock is generally associated with extreme weather events such as drought and flood. Both have the potential to mobilize dormant spores in the soil, increasing the potential for exposure to agricultural animals. Spores remain potent for many years, and in some areas present-day cases of anthrax in cattle cluster along trail routes that were active in the 19th century. Outbreaks of anthrax can and do occur in wild animals, especially when weather conditions allow for dormant spores to become airborne.⁹ It is thus reasonable to speculate that climate change might alter the current situation. Although I did not find empirical research on such a scenario, an increase in droughts or flooding followed by wind-borne movement of soil could theoretically lead to human exposure from naturally occurring anthrax spores. Such an eventuality would also create new issues for livestock producers. Regulatory oversight for anthrax and the anthrax vaccine occurs at the state level, and though reporting of incidents is required everywhere, other regulations vary from state to state. Some states require that the vaccine be distributed by veterinarians, and in states where anthrax has not been observed for many years, use of the vaccine may require approval from the State Veterinarian or Animal Health Official. The USDA APHIS National Surveillance Unit (NSU) collects reports of anthrax cases through the National Animal Health Reporting System (NAHRS).¹⁰ Existing procedures for slaughter and meat inspection in the U.S. make it exceedingly unlikely that gastronomic exposure would ensue in the event of an outbreak, though the emergence of alternative supply chains can theoretically pose new challenges in this area as well. In

⁸ Texas Department of State Health Services, History of Anthrax—Anthrax Through the Ages, Accessed July 18, 2012, at: http://www.dshs.state.tx.us/preparedness/bt_public_history_anthrax.shtm

⁹ CBC News. Anthrax likely killed 128 buffalo in the N.W.T., *CBC News North*. Accessed July 18, 2012 at: <http://www.cbc.ca/news/canada/north/story/2012/07/06/north-bison-anthrax-outbreak.html>

¹⁰ Dr. Steve Halstead, State Veterinarian for Michigan advises that the current national status of anthrax is listed as “sporadic/limited distribution” on the NAHRS reporting page: http://www.aphis.usda.gov/vs/nahss/disease_status.htm#cattle The National Animal Health Surveillance System (NAHSS) NAHRS 2011 Annual Report reports that three states reported bovine anthrax cases, one each in the Western Region, North Central Region, and Southern Region. This same report provides the following summary information for previous years: 2010/3 cases, 2009/4 cases, 2008/6 cases, 2007/3 cases, 2006/3cases, 2005/6 cases, 2004/2 cases. Additionally, ovine/caprine anthrax cases were reported in 2010 (one case), 2008 (one case), and 2005 (two cases). Individual state reports are not available. Additional information on the NAHRS can be obtained at: <http://www.aphis.usda.gov/vs/nahss/nahss.htm> or by contacting Dr. Stan Bruntz, NAHRS coordinator, at stanley.d.bruntz@aphis.usda.gov or 970-494-7246. In addition, Dr. Halstead provided answers to me for the following three questions: What controls are in place for oversight of anthrax vaccine? How much is used? In what species, and why or under what conditions? His answer (referring to Michigan) was:

1. I as the state veterinarian have statutory authority and responsibility for approval of biologicals for sale and distribution, and as such have never had a request to approve an anthrax vaccine. Neither of my predecessors in the SV position dating back to 1987 approved an anthrax vaccine, so no products are available for sale or distribution at present. Anthrax is not a condition of concern to livestock producers in our state.
2. None to my knowledge, and
3. N/A

Dr. Halstead also circulated the same questions to animal health officials in other states on my behalf. Many Eastern and Midwestern states are similar to Michigan. I provide a summary of replies he received from states where anthrax continues to be observed in livestock herds as an Appendix to my testimony for background information to the Committee.

general, veterinarians training and experience with the disease in cattle, bison, sheep and horses should be regarded as a resource should future exposure to humans occur from any source.

There are, however, numerous differences between the public health context and the way that plant and animal diseases raise ethical issues in the context of food production. The ethical responsibilities of agriculture reside first in assuring an adequate and robust supply of calories, and second in terms of insuring the safety of the food supply. The economic viability of the farm household is also crucial owing to the prevalence of farming and animal husbandry among those living in extreme poverty around the globe. Impacts on relatively small producers have significance in the U.S., as well. Although Europe and Japan successfully implemented significant improvements in their ability to monitor animal disease in the wake of the mad cow and foot and mouth outbreaks of the 1990s, small scale beef and dairy producers in the United States have lodged strenuous protests against such measures. Thus in many cases, the ethically appropriate strategy for controlling disease in an agricultural context is to minimize economic impact on producers. This may involve culling animals or destroying diseased crops, rather than taking measures to restore them to health. Cost concerns also apply to preventative therapies such as vaccination. For example, although vaccinations for foot and mouth disease exist they are not widely used even in some areas where this highly contagious disease is known to be prevalent.¹¹ In virtue of the relatively undeveloped interaction between agricultural and human bioethics, it is simply not clear as to whether these ethical concerns, which are deeply relevant in the context of developing policies for disease management in the food system, have implications for the deliberations of the committee.

Appendix: Summary of Replies from State Animal Health Officials (See Note 9)

Minnesota: Anthrax vaccine can only be distributed to producers in Minnesota by veterinarians. Vaccine usage is not tracked. After a bad year there is always a lot used, but like other states usage drops off with time and no new infection. Vaccine use is encouraged every spring in our newsletter for our endemic areas with recent infection. It is primarily used in beef cattle with an occasional horse vaccinated.

Nevada has areas with endemic anthrax. Therefore, use of vaccine is encouraged in cattle to prevent a constant “re-seeding” of the soil. However, after an episode within a herd, owners routinely vaccinate for a few years and commonly forget their previous problem. When conditions of drought or flooding (not this year) occur, disruption of the soil lends itself to anthrax events in our State.

Anthrax is endemic in South Dakota. Vaccine is widely available to livestock producers under no restrictions in South Dakota through private practitioners. It has been approved for use under the authority of the state vet, as you noted, and livestock producers are regularly encouraged to consider its use in routine vaccination programs. Typically it is used in cattle and bison, although it is also used in horses and sheep. Similar to Nevada, herds vaccinate for several years after experiencing an outbreak, and then complacency kicks in after some short-term memory failure. It is probably important to educate a presidential committee that Anthrax was a disease of livestock long before it became a bioterrorism concern. It’s an old disease with a cost effective prevention.

Nebraska is in an anthrax “endemic zone” with many states to our north, south and west. We have an anthrax situation from time to time—usually during years with wet springs followed by extreme heat and drought in the summer. In certain counties within the state, *Bacillus anthracis* spores lay underground, waiting for the right soil and temperature conditions to erupt. We’ve learned that there is usually a history that the pasture was a site of cattle and/or bison that died decades or a

¹¹ A. M. Hutber, R. P. Kitching, J. C. Fishwick, and J. Bires. "Foot-and-Mouth Disease: The Question of Implementing Vaccinal Control During an Epidemic." *The Veterinary Journal* 188, no. 1 (2011): 18-23.

century or more ago from anthrax. So across the state, cattle producers within certain endemic counties vaccinate for anthrax annually and routinely as part of normal herd management.

1. What controls are in place for oversight of anthrax vaccine? The State Veterinarian has statutory authority over the approval of anthrax vaccine. Colorado Serum produces the vaccine which is used prophylactically or on infected herds. Anthrax vaccine can be sold directly by accredited veterinarians to producers. Records of all anthrax vaccine sales and purchases prescribed and/or administered by an accredited veterinarian must be retained for at least 5 years. **Infected herds must be vaccinated**, and such vaccine shall be administered by an accredited veterinarian, the State Veterinarian, or the State Veterinarian's designee. An **exposed** herd may be vaccinated as deemed appropriate by the State Veterinarian.
2. How much is used? Varies from year to year. After an infected herd is found, there is typically a large vaccination response for a couple of years in the area--à tens of thousands of doses administered. It seems as time and years pass by with no infected herds, the use of vaccine dwindles. FYI: In 1999, I was "incident commander" for a 3 county outbreak of Anthrax in north-central Nebraska. A new generation of cow/calf producers had ignored their fathers'/grandfathers' advice about annual anthrax vaccination. That year was the "perfect storm" for anthrax, and we had many herds that had not been vaccinated in an area that had a history of anthrax in the 1930's and before. Long story short, I had dozens of herds quarantined, I personally vaccinated nearly 15,000 head of cattle in a 3 week period, and I treated at least 100 head that were manifesting early symptoms of Anthrax (in 1999, I discovered that extra-label use of Ampicillin IV was most successful, if you were fortunate enough to find them within the first 3-4 hours of symptoms). After that outbreak, vaccine sales and administration skyrocketed in the state. That number steadily decreased until 2005, when one herd was diagnosed in western Nebraska, and it made the 10:00 news. As expected, vaccine sales again spiked after this 2005 diagnosis. Now 7 years later, we find that vaccine purchases were made by only 6 veterinarians in 2011. Another "perfect storm" is brewing in the near future??
3. In what species, and why or under what conditions? Although anthrax vaccination is allowed in other species, it has only been administered to cattle and bison in Nebraska.

The Texas Animal Health Commission has statutory authority over the approval of biologics in Texas. The amount sold or used is not monitored. Texas has some endemic areas where one or two cases per year reported. Rules require infected herds to be vaccinated and quarantined. Quarantines are released 10 days after vaccination assuming disposal of the carcasses is also completed by burning and no new cases have been found. After the first case is reported though, usually the others in the area just vaccinate without reporting any more cases so they don't have to be bothered with a quarantine. According to the label the vaccine can be used in most livestock species. It can cause swelling near the injection site in horses so they are usually vaccinated in the brisket area rather than the hip or neck. Public Health counterparts are always notified, and if there is more than an isolated case in a region a public meeting that includes both our animal health veterinary staff and a public health representative is usually held.

Montana requires that the Department of livestock (State Veterinarian) provide oversight:

Per Statute: [81-2-703. Documents required for importation -- exemptions](#). (1) Except as provided in subsection (6), an animal, animal semen, or animal biologic may not be brought into the state without a permit and a health certificate.

Per Rule: [32.3.1001 HANDLING OF LIVE ANIMALS; VACCINATION](#), (3) Anthrax spore vaccine must not be used in any district unless a positive diagnosis of anthrax has been made by competent authorities, and then only by a deputy state veterinarian., and

Per Rule: [32.3.2301 CONTROL OF BIOLOGICS](#), (4) The distribution, sale or use of viable anthrax vaccines is prohibited except by permit from the state veterinarian of Montana.

Numbers of doses are approximates (MT is the only state that had or provided estimates of doses used).

2005: 60
2007: 1,000
2008: 10,500
2009: 8,000
2010: 8,000
2011: 8,000

Species impacted is primarily bovine, mostly domestic bison